K042003

SEP - 1 2004

510(k) SUMMARY

as required per 807.92(c)

1. Submitters Name, Address:

Draeger Medical Systems, Inc.
16 Electronics Avenue
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879
Contact person for this submission: Penelope H. Greco
Regulatory Submissions Manager

Date submission was prepared: July 23, 2004

2. Trade Name, Common Name and Classification Name:

A. Trade Name:

Infinity Trident NMT Pod

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Classification Number	Class	Regulation Number
Stimulator, Nerve, Peripheral, Electric	KOI	II	868.2775

3. Predicate Device Identification:

Organon Teknika Corp.
Tof-Watch Sx
K992598

4. Device Description:

The Infinity Trident NMT Pod is an addition to Draeger Medical Systems' Infinity patient monitoring series that provides automatic measurements of muscle response to electrical stimuli transmitted via surface electrodes placed over a peripheral nerve. The NMT sensors capture the muscle response as well as skin temperature. The pod then processes this information and relays it to the Infinity patient monitor for display.

5. Intended Use:

The Infinity Trident NMT pod is intended for use as an objective neuromuscular transmission monitor that measures the muscle response to electrical stimulation of a peripheral nerve.

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6. Comparison to predicate device

Similar to the TOF-Watch SX, the Infinity Trident NMT pod measures Train of Four (TOF), Post Tetanic Count (PTC), and Single Twitch Percentage.

7. Assessment of non-clinical performance data for equivalence:

The Infinity Trident NMT pod was tested in accordance with applicable standards and internal design control procedures and was determined to be as safe and effective for its intended use as the predicate device.

8. Assessment of clinical performance data for equivalence:

The analysis of the data collected demonstrates that the measurement values of the test device are equivalent to that of the referenced predicate device.

9. Biocompatability:

Not applicable

10. Sterilization:

Not applicable

11. Standards and Guidances: IEC 60601-1

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 1 2004

Ms. Penelope H. Greco
Regulatory Submissions Manager
Draeger Medical Systems, Incorporated
16 Electronics Avenue
Danvers, Massachusetts 01923

Re: K042003
Trade/Device Name: Infinity Trident NMT Pod
Regulation Number: 21 CFR 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: II
Product Code: KOI
Dated: July 23, 2004
Received: July 24, 2004

Dear: Ms. Greco:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

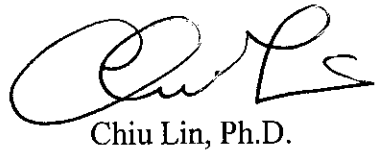
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known):__

Device Name: **Infinity Trident NMT Pod**

Indications for Use:

The Infinity Trident NMT pod can be used as an objective neuromuscular transmission monitor that measures the muscle response to electrical stimulation of a peripheral nerve.

Prescription Use_____✔_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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